Medicines Policy: The Role of Legislation

Asia Pacific Conference on National Medicines Policy

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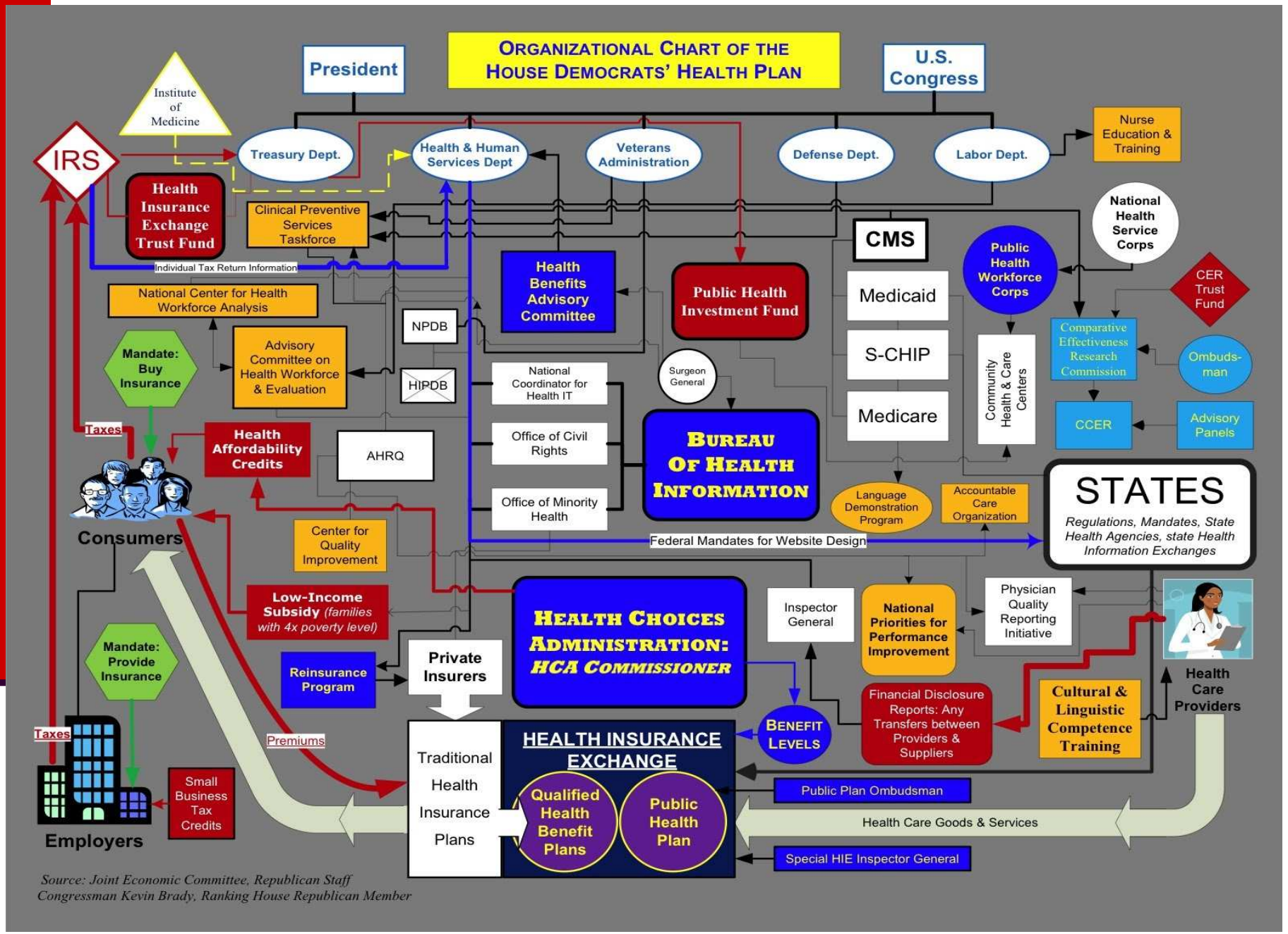

ORGANIZATIONAL CHART OF THE HOUSE DEMOCRATS' HEALTH PLAN
President
U.S. Congress
Institute of Medicine
IRS
Treasury Dept.
Health & Human Services Dept
Veterans Administration
Defense Dept.
Labor Dept.
Nurse Education & Training
Health Insurance Exchange Trust Fund
Individual Tax Return Information
Clinical Preventive Services Taskforce
National Center for Health Workforce Analysis
Advisory Committee on Health Workforce & Evaluation
Mandate: Buy Insurance
Taxes
Health Affordability Credits
Consumers
NPDB
HIPDB
Health Benefits Advisory Committee
Public Health Investment Fund
CMS
Medicaid
S-CHIP
Medicare
Public Health Workforce Corps
National Health Service Corps
CER Trust Fund
Comparative Effectiveness Research Commission
Ombuds-man
CCER
Advisory Panels
Community Health & Care Centers
National Coordinator for Health IT
Office of Civil Rights
Office of Minority Health
Surgeon General
BUREAU OF HEALTH INFORMATION
AHRQ
Language Demonstration Program
Accountable Care Organization
STATES
Regulations, Mandates, State Health Agencies, state Health Information Exchanges
Federal Mandates for Website Design
Center for Quality Improvement
Low-Income Subsidy (families with 4x poverty level)
HEALTH CHOICES ADMINISTRATION: HCA COMMISSIONER
Inspector General
National Priorities for Performance Improvement
Physician Quality Reporting Initiative
Mandate: Provide Insurance
Reinsurance Program
Private Insurers
Health Care Providers
Taxes
Premiums
Small Business Tax Credits
Employers
Traditional Health Insurance Plans
HEALTH INSURANCE EXCHANGE
Qualified Health Benefit Plans
Public Health Plan
BENEFIT LEVELS
Financial Disclosure Reports: Any Transfers between Providers & Suppliers
Cultural & Linguistic Competence Training
Public Plan Ombudsman
Health Care Goods & Services
Special HIE Inspector General
Source: Joint Economic Committee, Republican Staff
Congressman Kevin Brady, Ranking House Republican Member

“Social deprivation is not a matter of fate. It is a marker of policy failure.”

WHO DG Dr. Mgt Chan

8/2008

Agenda

- Background on law
- Case studies
  - Bhutan
  - Palau
  - Vietnam
- Group Work
- Q, A & D

The Law touches everything

Cure4Kids

Some public health successes linked to laws but based on public health evidence.

- Smoking bans
- Zoning and land use
- Seat belt and helmet laws
- Blood alcohol limits
- Water fluoridation
- Food fortification
- Childhood immunization
- Quarantine
- Professional licensing
- Occupational safety
- Product standards

PROMESE/CAL evolution trends

2000-2001

- Development of new role as key stakeholder in health sector policies – new legal framework; universal health ins. , decentralize

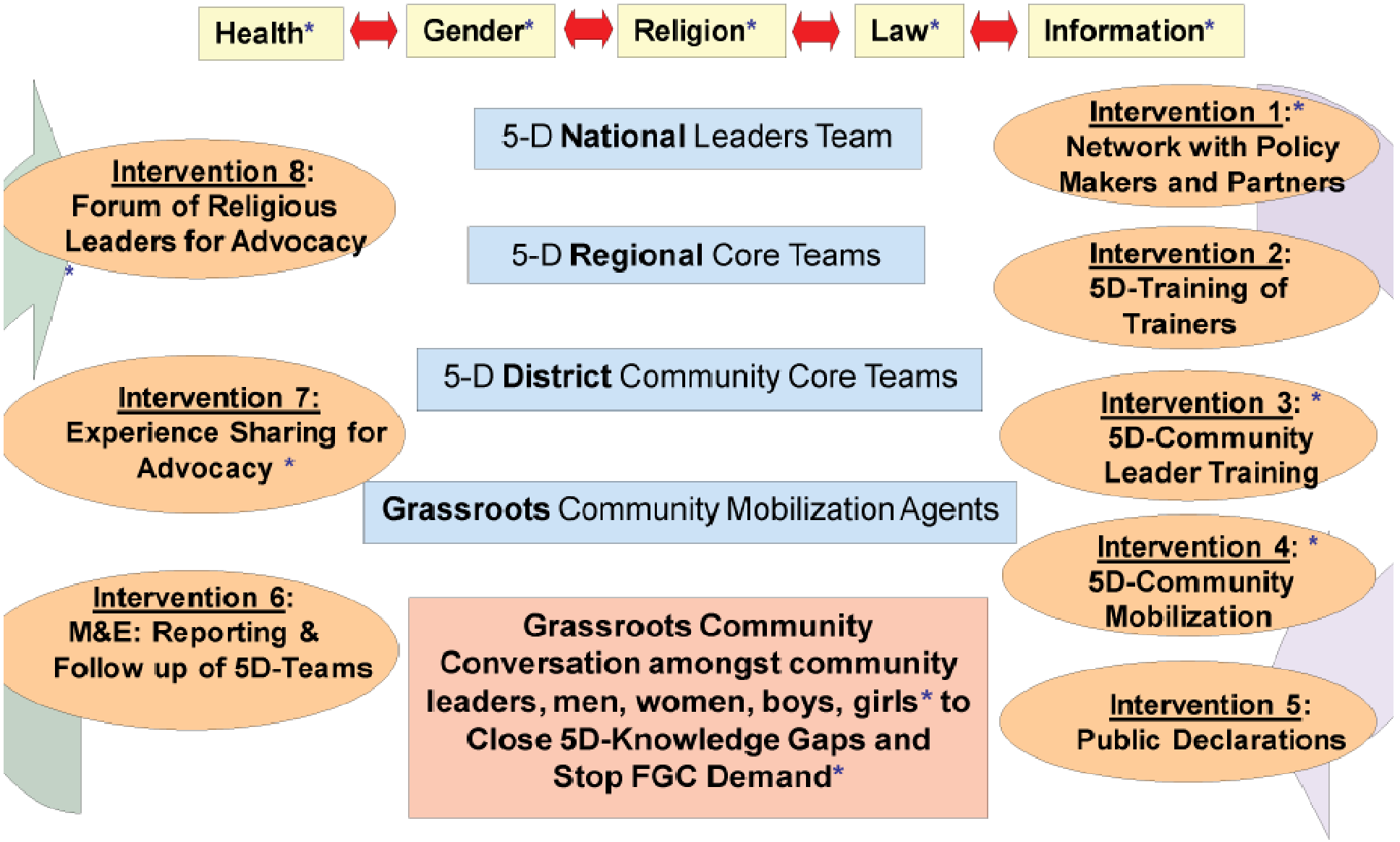
2004-2008

- Building institutional capacity and greater autonomy
- Development of business model with clearer accountability lines and more transparency

2008-2012

- Modernization of management processes
- Improving competitiveness of biddings and distribution

A 5-Dimensional Approach for the Eradication of FGC in Ethiopia



AID Policy on FGC: USAID Policy and Rationale of FGC, Effective 9/01/2000

Effective governance with law

Prof. Assoc.= NGO

- Albanian Pharmacists
  - NGO Formation
  - Governance structure
    - By Laws
    - Authority to self police
    - Separate from MOH

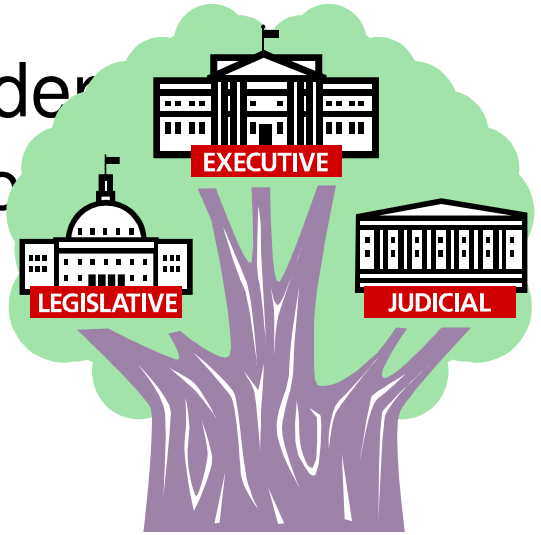
MOH Transition

- *Provider to regulator*
  - Nigerian health insurance regulation
  - Industry adopts primary health package

Outdoor legal clinic

Definitions

- International laws – treaties, customary law
- Constitutional provisions
- Executive powers – decrees, orde
  - Regulations – administrative pro
- Legislation - statutes
  - Sub-national ordinances
- Court rulings – judge made law
- Standards, codes, models and guidelines
- Policies are not law but
  - can be effective as a regulatory tool.



Definitions

- Governance – manner of governing - exercise of authority within an organization or system – management or control of something.
- To *regulate*: to control, organize, command, systematize, coordinate, take charge of, make plans for, put in order.
  - Done by law, regulation, policy, procedure, forms, and management.
- Good governance is effective, equitable, participatory, accountable, transparent, responsive, inclusive *and*
  - Follows the Rule of Law, a set of *universal* principles

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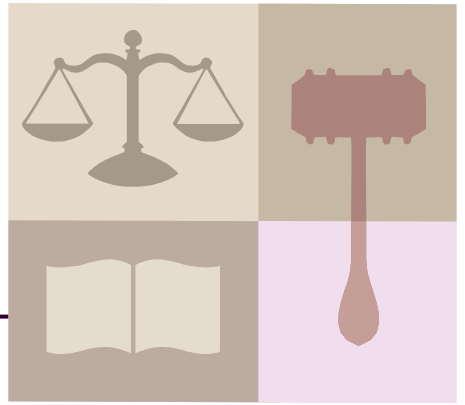
Rule of Law Goals, Results and Requirements



- **Goals - Government bound by the law**
  - Order and security
  - Checks and balances – separation of powers
  - Fairness and Access to justice
    - Procedural fairness
    - Equal and effective application of the law
- **Requirements**
  - Institutions
    - Well-functioning independent courts
    - Effective law enforcement agencies
    - Legal professionals
    - A comprehensive body of laws
      - Accessible in paper or electronically, language
      - Protection of human rights and civil liberties

The law is a domain of public health practice ASPH 2006

- **Core disciplines**
- **Operational and competency domains**

1. **Analytics/Assessment** – define a problem – is the law a factor in the desired health outcome?
2. **Policy development** –***articulate the*** health, fiscal, ***legal,*** administrative, social and political ***implications*** of each policy.
3. **Leadership and systems thinking skills** - ***use legal*** and political system to effect change

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Health-Legal Partnerships

- Goal – prioritize legal tools-part of standard of care
- History
  - Targeted diseases or populations: AIDS, children
  - Forms:
    - Pro bono, legal aid, legal check-up, direct legal services
      - to individuals or for populations
    - Training and curricula, individual and systemic advocacy
  - Prevention, triage, problem solve
  - Structure
    - On site legal clinics at ambulatory and in-patient units
    - Monthly or weekly intake
    - Training for physicians - - create awareness
  - ***Empirical research demonstrates cost savings***

Blue Print for How It Works

- Lawyers are part of the public health team and deal with the non-biological factors.
  - Able to do early screening and identification of legal problems
  - Implement effective interventions based in law
  - Deploy basic legal tools – contracts, litigation, etc
  - Knowledge on how to navigate decision making systems
  - Expertise in asserting different types of legal authority
  - Trained in the art of advocacy and persuasion

Operational approaches to law in pharmaceutical governance – how to?

- Integrate law as a cross cutting technical area
- Assess: Is the law useful, essential or an impediment to accomplishing a goal or solving a problem?
- Implement legal interventions Apply/enforce/augment laws and regulations. Utilize basic legal mechanisms
  - Mechanisms - tax, spend, regulate, incentivize
  - Remedies – sanctions, fines, suspensions, jail
  - Tools – damages, equitable relief, torts
  - Contract law
- Tag Team, use/build local capacity
- Collaborate with other ministries
- Health communications – "*click it or ticket*"
- Disseminate best practices, models, legal tools

Medicines Policy, the system, actors and other sectors

- Medicines Policy
  - Regulators - Health and non-health
    - Registration, selection, inspection,
    - R&D – clinical trials
    - Litigation tort
  - Supply Chain
    - Procurement – Contracts to ensure quality
  - Manufacturing and distribution
    - Prescription and Dispensing - pain medicines
  - Health Finance
  - Who or what else?

Law used as a framework for a functioning DRA/health system

- Ministry of Health and DRA functions
  - Policy development - stewardship
  - Funding – resource generation
  - Program and/or service delivery
  - Regulation of others
  - Coordination *of its own functions and with others*
- Law establishes the agency
  - Vests it with legal mandates
  - Creates the infrastructure, processes, and capabilities to perform its functions
- Common problems result from insufficient legislation

Bhutan

- Legislating Process and Content

Bhutan Constitution

Article 9 Principles of State Policy

- 21. The State shall provide free access to basic public health services in both modern and traditional medicines.
- 22. The State shall endeavor to provide security in the event of sickness and disability or lack of adequate means of livelihood for reasons beyond one's control.

There is more than health law.

- **All Laws**

  Administrative / Public Law / Agriculture Law / Banking Law / Civil Law / Commentated Laws / Commercial Law / Communications And Media Law / Company Law / Constitutional Law / Construction Law / Criminal Law / Electoral Law / Energy Law / Environmental Law / Health Law / Intellectual Property Law / Labor Law / Law Sources / Litigation And Court Procedure / Mining Law / Tax Law / Transport And Maritime Law

  Health Law

- Food Act of Bhutan 2005
  Food Rules and Regulation of Bhutan 2007
  Medical & Health Council Act (2002)
  Medicine Act of Bhutan 2003
  Medicines Rules and Regulations 2005
  The Medical and Health Council Act, 2002 of the Kingdom of Bhutan
  Tobacco Control Act of Bhutan 2010 (Dzongkha)

Bhutan NMP

10.2 **Health Legislation and Regulation**

a. Any health interventions not exclusively captured in the policy statements / all health interventions shall be carried out in compliance with the existing health related Royal Decree, Constitution of Bhutan, Acts and Regulations of Bhutan along with international and regional conventions, resolutions and treaties.

b. A comprehensive regulatory system shall be instituted to regulate the quality, safety, equity and efficiency of health services. This regulatory system then shall apply to all the health care facilities and services in the country.

e. Drug Regulatory Authority shall safeguard the human and animal health against harm resulting from the spurious quality of medical products available in the kingdom.

Legislating – the process

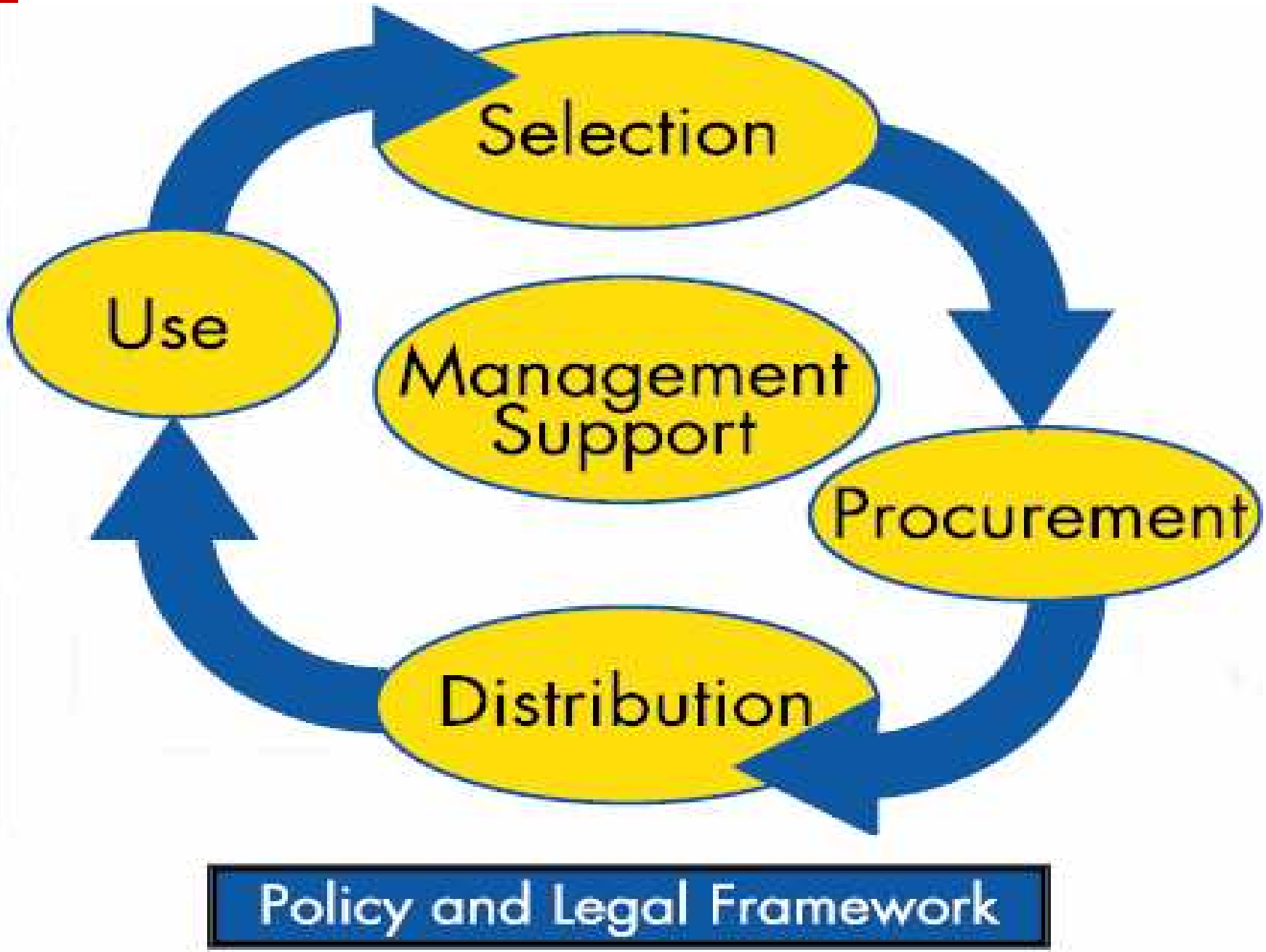
- Stakeholder consultation
  - Identify
  - Engage
  - Listen to what they are saying or not saying…….
- Importance of the right team
  - Use pharmaceutical and legal experts
  - Add MOJ, law enforcement, legislators, champions, MOH lawyer
  - But do involve people from service delivery level
- Assessment - determine relationship and linkages between pieces of legislation in place or under review
- Advocacy – walk the draft through channels, obtain political buy-in

Legislating – the content

- Be clear on policy principles
- Law is hierarchical – follow from the top
- Use an enabling approach in the Acts - details in regulations, rules, schedules, by- laws
- Legislation must be practical
  - Challenges in a small country
  - Differences between different settings – urban/rural
  - Knock on effect e.g. regulation of medicine for human/veterinary use
- Use regulatory underpinnings- ask are you authorized to do it?
- Think systematically and draft same way

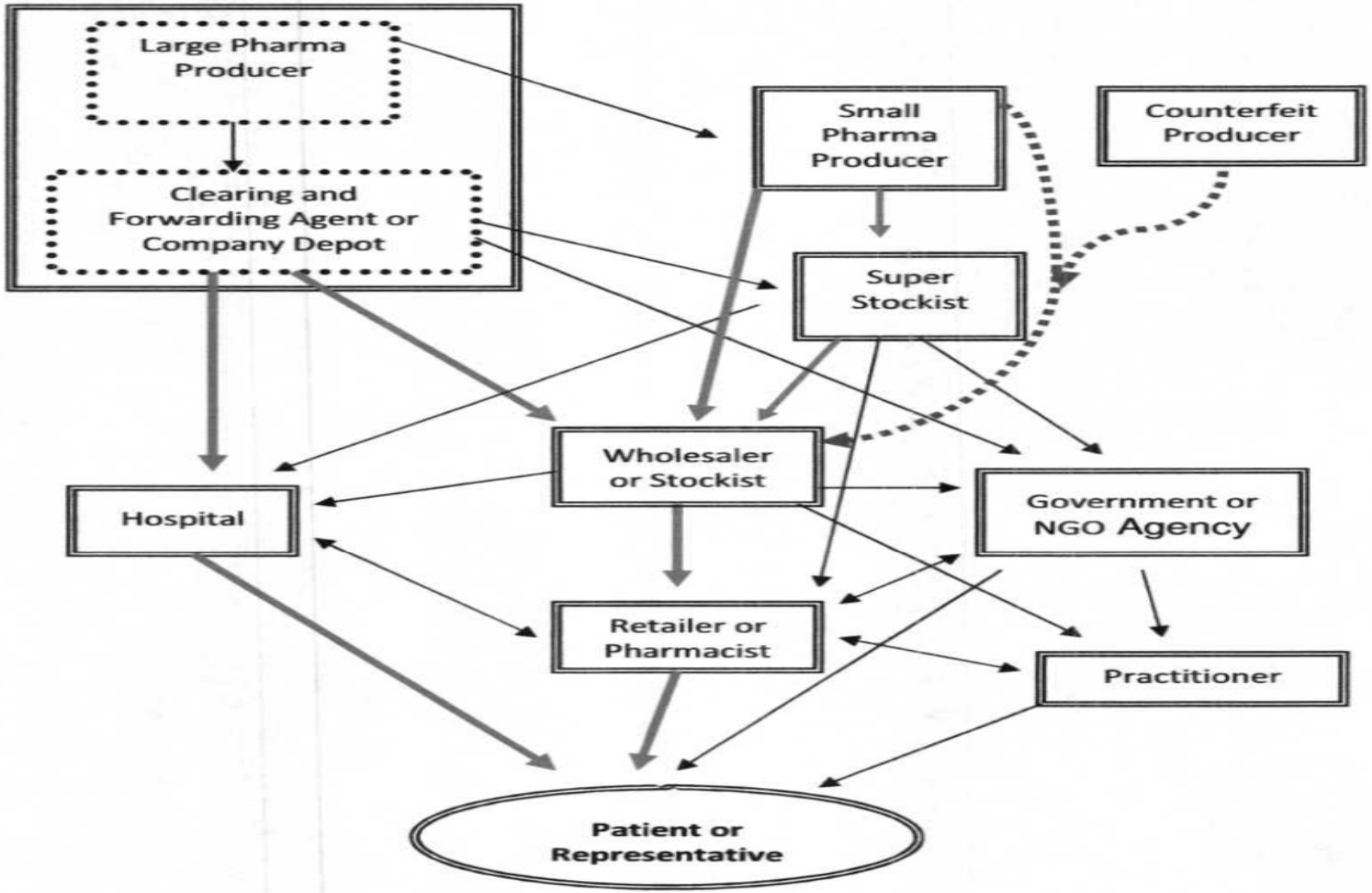
Legislating – some general principles

- Legislation is open to interpretation
- Must support and enable service delivery
- Sometimes people hide behind legislationl
- Importance of building capacity in
  - drafting
  - implementing
  - interpreting and understanding
  - monitoring impact of legislation
- Legislation is not as scary as it looks!


Selection
Procurement
Distribution
Use
Management Support
Policy and Legal Framework

Palau

- Procurement



Patterns of distribution of pharmaceuticals in India

Key

Main channels

Other channels

Channels for counterfeit drugs

Pharmaceutical Procurement

- Of the three main problems **poor governance** is one along with information and capacity.
- What informants said.
  - No, old or inadequate procurement laws
  - Lack of *other* laws or their potential violation
  - Internal governance processes – within and between ministries
  - Corruption and counterfeiting

Legal Solutions Already Exist

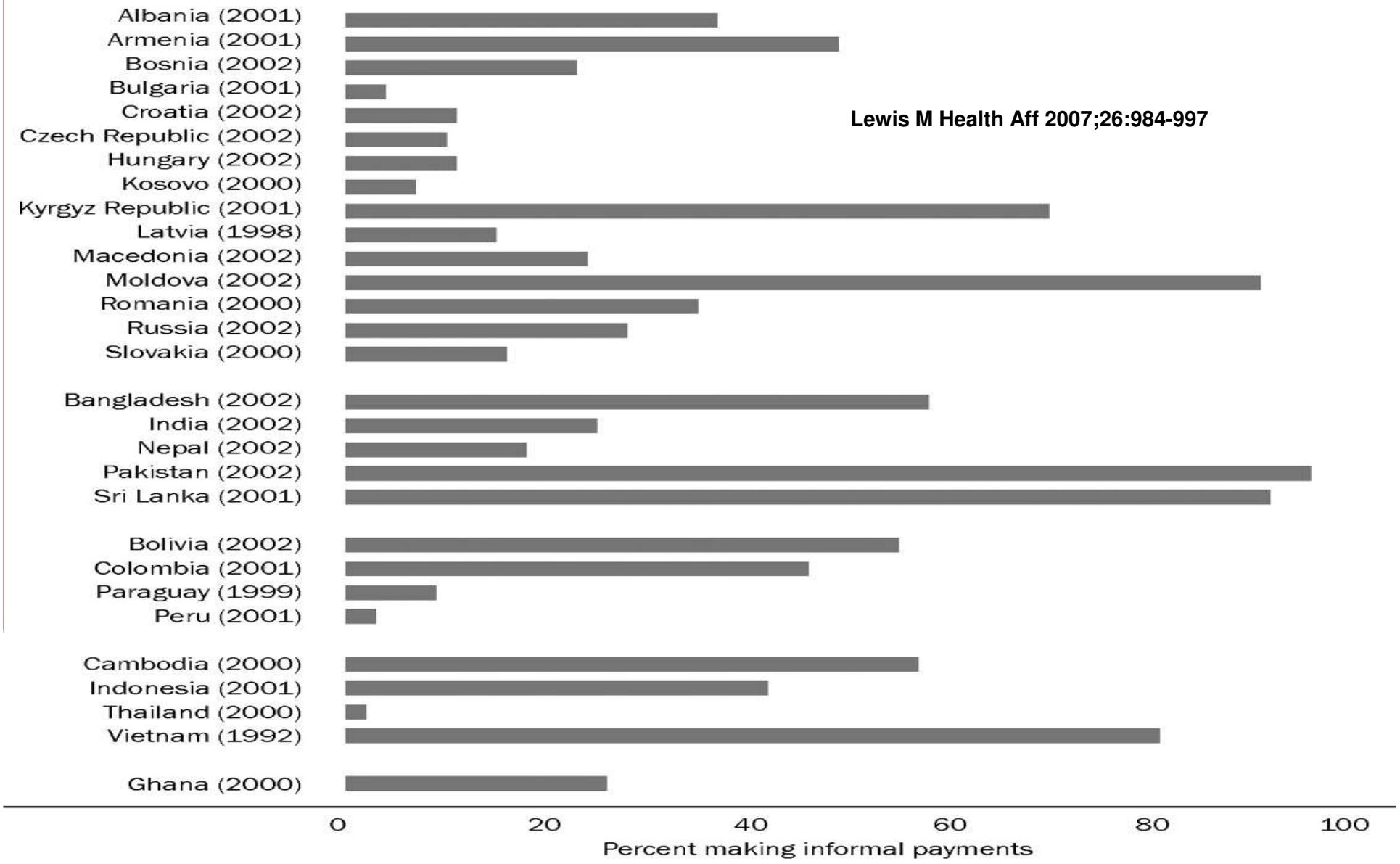
- National procurement laws; UNCITRAL Gov Procurement
- Most PMP = int'l business transaction - basic contract for the Purchase/Sale of Goods
- National and international laws and standards
  - Banking laws –letters of credit, payment
  - Customs – tariffs and quotas, NTBs
  - WB Standard Bidding Documents
- Long standing laws and practices.
  - UNCITRAL Convention on International Sale of Goods
  - UNIDROIT Law of Agents
  - Incoterms 2000 – Int'l Chamber of Commerce
- World Bank Training: Procurement Contract to Ensure Quality: an instrument of governance

Vietnam

- Informal payments
- Corrruption

EXHIBIT 1

Proportion Of Users Of Health Care Services Who Made Informal Payments, Various Countries, By Region, Selected Years 1992–2002



Lewis M Health Aff 2007;26:984-997

SOURCES: See Appendix I, online at http://content.healthaffairs.org/cgi/content/full/26/4/984/DC1.

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Poor governance and corruption in the pharmaceutical sector

- WHO GGM 26 countries
  - Uniform lack of access to laws, regulations and information on procedures
  - Ineffective and inefficient medicines regulatory systems – *weak institutions*
  - Counterfeits, substandard drugs and stock outs
- Solutions
  - Top down – laws and regulations
  - Bottom up – operationalize the law

Legal Solutions already exist

- UN Convention Against Corruption 2003
  - Member countries: 140 Signatories and 160 Parties – Vietnam is a member and has ratified the convention since 2009.
  - Status list: look up your country!

http://www.unodc.org/unodc/en/treaties/CAC/signatories.html

Group Project

- Identify one problem for legal discussion and select one participant to present the problem.
- Determine what steps you would take to solve the problem in your country. What do you think is the answer? What questions do you have?
- Describe what your plan might be to establish a public health legal partnership in your country and who would you ask to join?

Leverage the Law!

- To achieve the goal of strong pharmaceutical systems it is essential to include interventions based in law.
- Thank you for participating today.

- If you have any questions please feel free to contact me at:

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